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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,675	07/17/2003	Paul F. Predki	0618.019.0002	3642
57904	7590	09/12/2006		
CASTELLANO MALM FERRARIO & BUCK PLLC 1250 CONNECTICUT AVENUE NW SUITE 200 WASHINGTON, DC 20036				
			EXAMINER MARTIN, PAUL C	
			ART UNIT 1655	PAPER NUMBER

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,675

Applicant(s)

PREDKI ET AL.

Examiner

Paul C. Martin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1, 4-10 and 15-20) in the reply filed on 06/12/06 is acknowledged. The traversal is on the ground(s) that the inventions are not independent and distinct and that there would be no serious search burden to search all of the claims. This is not found persuasive because of the reasoning set forth in the action mailed 12/12/05 repeated here: In the instant case, the different inventions are directed to methods that are both physically and functionally distinct, and the particulars of one Group are not required for another. For example, Group I relies upon the broad comparison of a plurality of amino acid sequences in a region of a target protein with a plurality of amino acid sequences in a region of a cross reactive protein and identifying an amino acid sequence with the highest average homology in the first plurality. Groups II and III involve steps and conditions not found in Groups I or IV, for example the step of evaluating the degree of homology for each n-amino acid window of a plurality of amino acid windows of a target protein, when n is a number between 6 and 25. Group IV involves a computer system, hardware and programs that are physically and functionally distinct methods not found in any of Groups I-III.

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Group III involves the method step of assigning a score for each n-amino acid window comparison, wherein the score reflects the degree of sequence homology between two compared n-amino acid windows, a functionally distinct method step not found in any of Groups I, II, or IV.

The fact that inventions I-III are found in the same class/subclass does not abrogate the search burden of searching the three independent and distinct inventions as current searching techniques are directed to word-based search strategies and not class/subclass.

Applicant's arguments regarding the prior species restriction/election are found to be persuasive and the requirement is withdrawn, however the Examiner has deemed that a further species restriction/election is still required.

This application contains claims directed to the following patentably distinct species:

- 1) degree of sequence homology
- 2) how the region of the target protein is identified
- 3) how the region of the cross-reactive protein is identified

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The species are independent or distinct because the degree of sequence homology if reflecting the degree of sequence *identity* is a much stricter definition of the sequence than that of sequence homology reflecting sequence *similarity*. A search for sequence identity is more exacting and precise than that merely searching for similarities and therefore a search of one will not necessarily lead to the other and as such the species are both independent and distinct. Further, the identification of the region of the target protein involves two unique and distinct embodiments, containing the binding site and being on the surface of the folded target protein. The two species are independent and distinct from one another in that a binding site and the surface of a target protein are unique in structure, function and location and a search for one will not necessarily lead to the other. Similarly, how the region of the cross-reactive protein is identified involves two unique and distinct embodiments, containing the binding site and being on the surface of the folded target protein. The two species are independent and distinct from one another in that a binding site and the surface of a target protein are unique in structure, function and location and a search for one will not necessarily lead to the other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1655

08/30/06



TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER